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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,035	02/27/2002	Robert Kincaid	1001011076-1	6480

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EXAMINER	
SMITH, CAROLYN L	
ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
10/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/087,035	KINCAID, ROBERT	
	Examiner	Art Unit	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,22,27,28,31-37,41-44 and 46-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,22,27,28,31-37,41-44 and 46-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In view of the appeal brief filed on 6/26/07, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

Applicant's arguments, filed 6/26/07, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-11, 22, 27-28, 31-37, 41-44, and 46-49 are herein under examination.

Claim Objections

Applicant is advised that should claim 42 be found allowable, claim 46 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11, 22, 27-28, 31-37, 41-44, and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhou et al. (US 2003/0120432 A1) further in view of Markowitz et al. (US 2003/0100999) and Cracauer et al. (US 20070178474).

The priority date relied upon for US 2003/0120432 A1 and 2007/0178474 A1 and comes from provisional applications.

Copies of the provisional applications are not included with this Office action, because the copies could not be readily obtained when the Office action was mailed. Should applicant

desire a copy of such a provisional application, applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 CFR 1.14(a)(1)(iv), paying the required fee under 37 CFR 1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless applicant can demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application is not readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge does not apply.

Zhou et al. describe a method for generating a custom probe array design wherein a system receives user-selected identifiers (array design parameters) (abstract), as stated in instant claims 1, 6, 22, and 45. Zhou et al. describe the user selecting probe set identifiers from a corresponding list that correspond to a gene (paragraph 0009). Zhou et al. describe a web portal processes inquiries regarding biological information and a user selects « probe set identifiers » which enable detection of nucleic acids and genes for microarray experiments (paragraph 0005) which represents a customer selecting at least one array design parameter and at least one gene of interest, as stated in instant claims 1, 22, 27, and 45. Zhou et al. describe the genomic portal system receives user-selected identifiers including sequence information, the system verifies probes corresponding to identifiers and generates a custom probe array design (paragraphs 0006 and 0008) and constructing and arranging arrays to detect and/or measure any one gene expression (paragraph 0007) which represents providing parameters to the vendor who curates the sequence and selects the probes specific for the curated sequence as mentioned in paragraph 0005, as stated in instant claims 1, 22, 27, and 45. Zhou et al. describe using remote vendor

business systems and servers (Figure 4, #404 and paragraph 0134), as stated in instant claims 1, 2, 22, 27, 31, and 45. Zhou et al. describe further generation including modifying or rejecting one or more user-selected probe array format factors including user-selected probe set identifiers and displaying this information to the user (paragraph 0010) which represents the vendor selecting at least one probe specific for the curated gene sequence, as stated in instant claims 1, 22, 27, and 45. Zhou et al. describe a verifier/designer performs an analysis of the user-provided input sequence to determine which portions of the sequence should be represented by probes because some portions may consist of short, common repeats that are not effective in uniquely representing the sequence as a whole (paragraph 0125) and using masks (paragraph 0063) which represents curating comprising removal of commonly repeated subsequences, as stated in instant claims 42-44, 46, and 48. Zhou et al. describe analyzing the complexity of the user-provided sequence and report that the sequence is insufficiently complex with too many repeats to be uniquely and/or reliably represented by a probe set (paragraph 0126). Zhou et al. describe a method and system (vendor) enabling a number of users to share space on an array or enabling a number of users to share in ordering portions of a lot of catalog probe arrays for economical benefit (paragraphs 0005 and 0006), which represents the vendor providing at least one additional array design parameter including probe selection as well as layout parameters, as stated in instant claims 1, 5, 27, 34, and 45. Zhou et al. describe synthesizing the probe arrays (paragraph 0010) which represents completing the array design and fabricating the array, as stated in instant claims 1, 22, 27, 28, and 45. Zhou et al. describe the user may select many probe array format factors such as number of probes, dimensions of probes, maximum number of probes representing one or more genes, substrate material (paragraph 0009) which represents the

user selecting "other" customer selected array design parameters, as stated in instant claims 33-36. Zhou et al. describe the user may select geographic dispersion of probe sets (paragraph 0009) which represents a customer selected array design layout and probe parameters, as stated in instant claims 5, 34, and 35. Zhou et al. describe using a probe set with controls, as stated in instant claims 7 and 36. Figure 14 shows a graphical user interface for providing options and design selections (paragraph 0039), as stated in instant claims 8 and 37. Figure 15 shows a graphical user interface for providing one or more custom probe array designs or probe set designs (layouts) (paragraphs 0010 and 0040) which represents visual display of array layout of at least one customer selected array design parameter, as stated in instant claim 9. Zhou et al. describe receiving probe set identifiers that identify potential probes and verifying probe sets of verified probes (paragraph 0007), which represents some probe selection by a vendor, as stated in instant claims 1, 27, and 45. Zhou et al. describe displaying the custom probe array design to the user via graphical user interface and receives a user selection specifying acceptance, modification, or rejection of the design (abstract and Figure 15), as stated in instant claims 10 and 11. The user acceptance of array design represents completion of the design by the vendor, as stated in instant claims 1, 2, 22, 27, 31, and 45. The user modification of the design represents completion of the array design by the customer, as stated in instant claims 1, 3, 22, 27, 32, and 45. Zhou et al. describe providing the user with the accepted or modified custom probe array (abstract). Zhou et al. describe using arrays for genes and nucleic acids (Figure 2 #230), as stated in instant claims 4, 22, and 27. Zhou et al. describe researchers using microarrays to determine which genes are expressed in certain cells or organs, extracting biological information, and designing follow-up experiments (paragraph 0004). Zhou et al. describe the probe set

identifiers may be selected by the user from a predetermined list where each item may correspond to an EST, gene, splice variant, or protein (paragraph 0009) which represents selecting at least one gene of interest and probe parameter for said gene, as stated in instant claim 27. Zhou et al. describe systems, methods, and computer program products to address these needs, such as allowing the user to select probe identifiers that may be associated with probe sets of one or more probes that are capable of detecting genes of interest, which are then correlated with data and/or products to be provided to the user (paragraph 0006), as stated in instant claim 27. Figures 7A and 10 show displaying and providing genomic data, sequence data, expression data, and various other forms of information to the user (paragraphs 0030 and 0034), as stated in instant claim 27. Zhou et al. describe synthesizing probes on a substrate (paragraph 0090), as stated in instant claim 28. Zhou et al. describe selecting substrate material or design and synthesized probe arrays (paragraph 0010), as stated in instant claim 28. Zhou et al. describe constructing probe arrays to detect or measure one or any combination of biological information including gene expression, genotype, cells, cellular membranes, and organelles (paragraph 0007) which represents an in situ array, as stated in instant claim 41. Zhou et al. provisional (60/301,298) does not specifically state curating or curated sequence (instant claim 1, steps c) and d)) or describe all of the curating limitations in claims 42-44 and 46-49.

Markowitz et al. describe offering gene chip technology manufacturing glass microarrays with probes (0006). Markowitz et al. describe using custom gene sequences (0037), user selection and user-selected gene attributes (parameters) (0110, 0229) allowing users to specify parameters and adjust parameters (0050), sequence based matching and manual data curation including detecting potential sequence data contamination (0043, 0046), and sequence searching

for a user-provided nucleotide sequence against a database of GenBank sequences corresponding to Affymetrix (vendor) probe sets (0249) which represents curating a sequence and selecting at least one probe specific for a curated sequence, as stated in steps c) and d) of instant claim 1. Markowitz et al. describe the user entering search parameters with the search completing by listing Affy fragments that match the input sequence (0253) and the Gene Set Import Utility allowing a user to create a Gene Set based on a list of Affy probe set names wherein the user-selected return attribute values are queried followed by displaying the query results after which the user can save the fragments if he/she wishes (0255, 0245) which represents completing the array design by the customer, as stated in instant claim 3. Markowitz et al. do not describe all of the curating limitations in claims 42-44 and 46-49.

Cracauer et al. describe a high-throughput olignucleotide production system (claim 1), designing and producing detection assays for target sequences (0434), and receiving orders from a customer who enters a target sequence into a web interface, processing orders, and designing the detection assays which can be produced and shipped to customers (0435, 0539). Cracauer et al. describe a curated sequence (0484), checking for errors in target sequence and removal of artifacts associated with sequence assembly and removal of commonly repeated subsequences (0443-0444, 0470-0475, 0541, 0101, 0369, 0505, 0653) as stated in instant claims 42-44 and 46-49.

Zhou et al. state researchers are increasingly challenged to extract biologically meaningful information from the vast amounts of data generated by microarray technologies and to design follow-up experiments (0004). Cracauer et al. state attempts to analyze individuals based on a reference genome sequence will often fail (i.e. probes based on reference sequence

fail to hybridize to target sequence in another individual) because the target sequence for many individuals differs from the reference sequence (0022). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Zhou et al. by sequence searching for a user-provided nucleotide sequence against a database of GenBank sequences corresponding to Affymetrix (vendor) probe sets as taught by Markowitz et al. wherein the motivation would have been to provide a common interface for multiple databases in a relational format to support efficient exploration and analysis, as stated by Markowitz et al. (0009) in order to extract meaningful information, as stated by Zhou et al. (0004). It would have been further obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of Zhou et al. and Markowitz et al. by checking for errors and removal of sequence artifacts as taught by Cracauer et al. where the motivation would have been to select appropriate target sequences that can be successfully targeted by detection assays (0442) in order to extract meaningful information (Zhou et al. 0004).

Thus, Zhou et al. in view of Markowitz et al. and Cracauer et al. make obvious the instant invention.

Applicant argues that Zhou et al.'s provisional (60/301298) does not disclose a vendor curating a sequence for a gene of interest identified by a user and then selecting probes for the curated sequence (i.e. claim 1), a user/customer completing the array design (i.e. claim 3), and curating that includes checking the sequence for errors, removing commonly repeated subsequences, and/or removing any artifacts associated with sequence assembly (i.e. claims 42-44 and 46-49. While not fully agreeing with Applicant's arguments, they are deemed moot due

to the addition of new prior art references that have been added to strengthen the 35 USC 103 rejection above.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

October 13, 2007

/Carolyn Smith/
Primary Examiner
AU 1631

Marjorie A. Moran
SPE, AU 1631